

REMARKS

The Office Action dated July 7, 2009 has been received and reviewed. Claims 1 to 19 are pending in the application. Claims 1-19 are rejected.

Claim 1 is currently amended to include the feature “a biological sample containing two or more microorganisms”. Support for the amendment can be found in the application on page 5, lines 32-33, for example. Claim 1 is currently amended to include the feature “identifying two or more different micro-organisms present within the sample”. Support for the amendment can be found in the application on page 32-34, for example. Claim 1 is currently amended to include the feature “determining, in parallel, the effect of one or more antimicrobial(s) on the two or more different micro-organisms from the sample, wherein determining the effect of one or more antimicrobial(s) comprises adding an antimicrobial at a pre-determined concentration to the sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the two or more different micro-organisms, and assessing the number of each one of the two or more microorganisms in the sample at the end of the pre-determined time period”. Support for the amendments can be found in the application on page 5, line 32 to page 6, line 1; and page 3, lines 18-19, for example. Claim 1 is amended to include the feature “wherein steps (a) and (b) are performed without prior separation of the two or more microorganisms”. Support for the claim can be found in the application on page 5, line 32 to page 6, line 4, for example.

Claim 18 is currently amended to include the feature “wherein analyzing the microorganism’s nucleic acid comprises determination-of comparing at least a part of the microorganism’s genome sequence to a known sequence.” Support for the amendment can be found in the application on page 2, lines 31-32, for example.

Claim 19 is currently amended to include the feature “wherein analyzing the microorganism’s nucleic acid comprises determination-of restriction fragment length polymorphism analysis or amplified rDNA restriction analysis.” Support for the claim can be found in the application on page 2, lines 34-36, for example.

Rejection Under 35 USC 102

The rejection of claims 1-10 and 13-15 under 35 USC 102(b) as being anticipated by Peck et al. US 5,789,173 Aug. 4, 1998 is maintained.

Claim 1 is currently amended to include the features of “identifying two or more different micro-organisms present within the sample” and “determining the effect of one or more antimicrobial(s) on the two or more different micro-organisms from the sample” wherein

the steps are “are performed without prior separation of the two or more microorganisms”. Claim 10 is currently canceled.

Peck et al. does not teach or suggest identifying two or more different microorganisms present within the sample. Peck et al. does not teach or suggest splitting a sample prior to or after the step of incubating the specimen in media embedded with antimicrobial agents to allow for the detection of two or more different microorganisms in the specimen. Peck et al. does not teach or suggest the use of a plurality of primer pairs for the detection of two or more different microorganisms in the specimen.

Furthermore, Peck teaches the generic detection of double-stranded DNA (e.g., through the use of intercalating dyes) to detect amplified DNA. A person of ordinary skill in the art will recognize that these reagents (e.g., intercalating dyes) and methods, *per se*, are not capable of distinguishing between the DNA from two or more different amplicons in a sample.

In summary, Peck et al. does not teach or suggest the detection of two or more different microorganisms from the sample, as claimed. Therefore, claim 1 is patentable over Peck et al. for at least the reasons discussed above. Claims 2-9 and 13-15 each add additional features to claim 1 and are likewise patentable over Peck et al.

Withdrawal of the rejection of claims 1-9 and 13-15 under 35 USC 102(b) as being anticipated by Peck et al. is respectfully requested.

Claims 1, 2, 4, 5, 6, 7, 12-15, 18 and 19 are rejected under 35 USC 102(b) as being anticipated by Cooksey et al. Journal of Clinical Microbiology, May 2002, p. 1651-1655.

Claim 1 is currently amended to include the features of “identifying two or more different micro-organisms present within the sample” and “determining the effect of one or more antimicrobial(s) on the two or more different micro-organisms from the sample” wherein the steps are “are performed without prior separation of the two or more microorganisms”.

Cooksey et al. expressly teaches the *prior separation* of microorganisms prior to antibiotic susceptibility testing discloses:

“Primary isolation and identification of MTC were performed at the MOHP laboratory, and cultures were sent to CDC in a coded fashion ...” (page 1652, column 1, under “Bacterial isolates”; emphasis added)

“Isolates of MTC were tested at CDC by the modified method of proportions...” (page 1652, column 1, under “Antimicrobial susceptibility testing, emphasis added)

Cooksey et al. does not teach or suggest identifying two or more different microorganisms present within a sample *without* prior separation of the microorganisms.

In summary, Cooksey et al. does not teach or suggest the detection of two or more different microorganisms from the sample, as claimed. Therefore, claim 1 is patentable over Cooksey et al. for at least the reasons discussed above. Claims 2, 4, 5, 6, 7, 12-15, 18 and 19 each add additional features to claim 1 and are likewise patentable over Cooksey et al.

Withdrawal of the rejection of claims 1, 2, 4, 5, 6, 7, 12-15, 18 and 19 under 35 USC 102(b) as being anticipated by Cooksey et al. is respectfully requested.

Rejection Under 35 USC 103

The rejection of claims 1-10, 12 and 13-15 under 35 USC 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4, 1998 is maintained.

Claim 1 is currently amended to include the features of “identifying two or more different micro-organisms present within the sample” and “determining the effect of one or more antimicrobial(s) on the two or more different micro-organisms from the sample” wherein the steps are “are performed without prior separation of the two or more microorganisms”. Claim 10 is currently canceled.

Claim 1 is patentable over Peck et al. for at least the reasons discussed above. Claims 2-9, 12, and 13-15 each add additional features to claim 1 and are likewise patentable over Peck et al.

Withdrawal of the rejection of claims 1-9, 12, and 13-15 under 35 USC 103(a) as being unpatentable over Peck et al. is respectfully requested.

The rejection of claims 1-11 and 13-15 under 35 USC 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4, 1998 in view of Bruno et al. Journal of Molecular Recognition, Vol. 9, 474-479 (1996) cited in IDS is maintained.

Claim 1 is currently amended to include the features of “identifying two or more different micro-organisms present within the sample” and “determining the effect of one or more antimicrobial(s) on the two or more different micro-organisms from the sample” wherein the steps are “are performed without prior separation of the two or more microorganisms”. Claims 10 and 11 are currently canceled.

Claims 1-9 and 13-15 are patentable over Peck et al. for at least the reasons discussed above. Bruno et al. discloses immunomagnetic (IM) *separation* and concentration of specific target ligands, such as bacteria, from complex mixtures.

Bruno et al. does not teach or suggest identifying two or more different microorganisms in a sample *without* prior separation. Thus, the modification of Peck et al. with Bruno et al. does not teach or suggest all of the elements of any one of claims 1-9 and 13-15.

Withdrawal of the rejection of claims 1-9, and 13-15 under 35 USC 103(a) as being unpatentable over Peck et al. in view of Bruno et al. is respectfully requested.

Claims 1-10 and 13-18 are rejected under 35 USC 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4, 1998 in view of Kohne et al. US 5,738,988 April 14, 1998.

Claim 1 is currently amended to include the features of “identifying two or more different micro-organisms present within the sample” and “determining the effect of one or more antimicrobial(s) on the two or more different micro-organisms from the sample” wherein the steps are “are performed without prior separation of the two or more microorganisms”. Claim 10 is currently canceled.

Claim 1 is patentable over Peck et al. for at least the reasons discussed above. Claims 2-9 and 13-18 each add additional elements to claim 1 and are likewise patentable over Peck et al.

Kohne et al. does not teach or suggest identifying two or more different microorganisms in a sample without prior separation. Thus, the modification of Peck et al. with Kohne et al. does not teach or suggest all of the elements of any one of claims 1-9 and 13-18.

Withdrawal of the rejection of claims 1-9, and 13-15 under 35 USC 103(a) as being unpatentable over Peck et al. in view of Kohne et al. is respectfully requested.

Claims 1-9 and 12-19 are rejected under 35 USC 103(a) as being unpatentable over Cooksey et al. Journal of Clinical Microbiology, May 2202, p. 1651-1655 in view of Kohne et al. US 5,738,988 April 14, 1998.

Claim 1 is patentable over Cooksey et al. for at least the reasons discussed above. Claims 2-9 and 12-19 each add additional elements to claim 1 and are likewise patentable over Cooksey et al.

Kohne et al. does not teach or suggest identifying two or more different microorganisms in a sample without prior separation. Thus, the modification of Cooksey et al. with Kohne et al. does not teach or suggest all of the elements of any one of claims 1-9 and 12-19.

Withdrawal of the rejection of claims 1-9, and 12-19 under 35 USC 103(a) as being unpatentable over Cooksey et al. in view of Kohne et al. is respectfully requested.

Claims 1-19 are rejected under 35 USC 103(a) as being unpatentable over Cooksey et al. Journal of Clinical Microbiology, May 2002, p. 1651-1655 and Kohne et al. US 5,738,988 April 14, 1998, as applied to claims 1-9 and 12-19, further in view of Bruno et al. Journal of Molecular Recognition, Vol. 9, 474-479 (1996) cited in IDS.

Claim 1 is patentable over Cooksey et al. for at least the reasons discussed above. Claims 10 and 11 are currently canceled. Claims 2-9 and 12-19 each add additional elements to claim 1 and are likewise patentable over Cooksey et al.

Kohne et al. does not teach or suggest identifying two or more different microorganisms in a sample without prior separation. Further, Bruno et al. does not teach or suggest identifying two or more different microorganisms in a sample without prior separation. Thus, the modification of Cooksey et al. with Kohne et al. and Bruno et al. does not teach or suggest all of the elements of any one of claims 1-9 and 12-19.

Withdrawal of the rejection of claims 1-9, and 12-19 under 35 USC 103(a) as being unpatentable over Cooksey et al. in view of Kohne et al. and in further view of Bruno et al. is respectfully requested.

Rejection Under 35 USC 112

Claim 1-19 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Patent Office alleges that claim 1 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although the Applicant believes that the previously-presented language of claim 1 is clear to a person of ordinary skill in the art, the Applicant currently amends claim 1 in order to advance prosecution. As amended, claim 1 now indicates that both step a) and step b) include the process of analyzing the microorganisms' nucleic acid.

Claims 18 and 19 are currently amended to eliminate the word "determination", which was objected to by the Patent Office as implying a mental step.

Claims 10 and 11 are currently canceled.

In view of the amendments to claims 1, 18, and 19, withdrawal of the rejection of claim 1-9 and 12-19 under 35 USC 112, second paragraph, as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention, is respectfully requested.

All outstanding objections and rejections are believed to have been met and overcome. If a telephonic conference with Applicants' undersigned representative would be useful in advancing the prosecution of the present application, the Examiner is invited to contact the undersigned at (651) 736-7430. A notice of allowance for all pending claims is respectfully solicited.

Respectfully submitted,



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